

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X
UNITED STATES OF AMERICA,

-against-

Case No.: 20 CR 160 (MKV)

SETH FISHMAN, DVM, and
LISA GIANNELLI

Defendants.

-----X

**REPLY IN RESPONSE TO GOVERNMENT'S OPPOSITION TO MOTION
TO DISMISS COUNTS ONE AND TWO OF THE SUPERSEDING
INDICTMENT**

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Defendants SETH FISHMAN, DVM and LISA GIANNELLI, file this Reply in response to the Government’s Opposition to Defendants” Motion to Dismiss Counts 1-2 (Dkt. 327 hereinafter “Motion”) in the Superseding Indictment. Dkt .335 (hereinafter “Opposition”).¹

Defendants request that your Honor grant the Motion and dismiss Counts 1-2 in the Superseding Indictment with prejudice. Defendants rest largely on the arguments previously raised in the Motion because, as set forth herein, none of what the Government has argued in its Opposition requires this Court to salvage this defective Superseding Indictment and endorse the Government’s virtually limitless application of the FDCA theory.

1. Defendants have not Advocated for the Limitation that the Government Argues in its Opposition.

As a starting point for consideration, the Government misreads Defendants’ argument. Defendants never asserted that Section 333(a)(2) of the FDCA cannot apply to a consignee, a wholesaler, end-user, or other person or entity in the drug supply chain. *See* Opposition at 31-32. Each of those persons are arguably “consumers” in the drug supply chain. Defendants have instead consistently

¹ In this Reply, Defendants cite to the page numbers at the bottom of the filed Motion and the Opposition not the ECF page number. For example, page 1 of the Opposition is ECF page number 8 and page 1 of the Motion is ECF page number 7.

contended (Dkt. 223 filed June 22, 2020) (Reply to Opposition to Motion for Bill of Particulars) that the Government has failed to state any violation of FDCA's felony penal provision, Section 333(a)(2), where, as here, that offense includes either state race commissions or racetracks as an object of that offense. *See Fed. R. Crim. P.* 12(b)(3)(B)(v). This is clear from the plain text of the FDCA, especially the dozens of provisions found at Section 331, its robust legislative history, the purposes underlying the FDCA, and the case law. Not a single U.S. decision has directly endorsed the government's view of the FDCA.

2. The Government Argues in favor of a Limitless Application of Section 333(a)(2) of the FDCA but Fails to Address the Plain Text of Sections 331 and Section 352 of the FDCA, the Purposes Underlying the FDCA, and More than One Hundred Years of Legislative History.

In its opening pages, the Government pronounces that the FDCA places no limitations on the object of the defrauding or misleading in Section 333(a)(2) and states: "*In every instance* in which a defendant commits a violation of the misbranding and adulteration laws set forth in § 331, that offense is a felony if, in the commission of that offense, the defendant acts with an intent to defraud or mislead." *See* Opposition at 10-11. (emphasis ours). Put simply, the Government asks this Court to interpret an ambiguous penal provision, Section 333(a)(2), to authorize the felony prosecution of any defendant who distributes, agrees to

distribute, or introduces or agrees to introduce any misbranded or adulterated drug from one state to another with the intent to defraud or mislead anyone.

In making this broad proclamation, the Government cites no decision which supports this premise and ignores the fact that where there is statutory silence, there is ambiguity. *See United States v. Grissom*, 645 F.2d 461 (5th Cir. 1981)²; *United States v. Smith*, 740 F.2d 734 (9th Cir. 1984). Furthermore, in formulating these sweeping pronouncements to further the limitless application theory of the FDCA, the Government fails to discuss or analyze the plain text of the statutory provisions found in Section 331 or 352 and ignores more than a hundred years of history underlying the FDCA. *See Motion*, at 7-21 (discussing the statutory text of FDCA including Sections 352 and 331 and other provisions along with the legislative history of FDCA and its predecessor statute). There is, for example, no discussion of the Section 331 or 352 provisions *Motion* at 6, n. 10; *Motion* at 7, n.11. The Opposition also ignores the predecessor Act, the Pure Food and Drug Act. Nowhere in that history, the history of the FDCA, or in the provisions of any Section 331

² In its Opposition, the Government downplays the significance of *Grissom*'s astute reasoning and claims there are no analogous federalism concerns here. Nonetheless, Florida law criminalizes conduct which is substantially similar to the conduct alleged in Counts 1-2 of the Superseding Indictment. *See Fla Stat Section 550.235(2)* (making it a felony "to conspire to administer or attempt to administer any medication prohibited by law to a race animal for purposes of affecting the outcome of a horserace.")

offense is there any indication that the FDCA may be extended as far as the Government says it should here.

3. The Government Relies Heavily on Dicta From *Arlen* that was based on Dicta from *Hatch* to support its limitless application of the FDCA theory

The single case upon which the Government heavily relies to sponsor this limitless application of the FDCA theory is a Seventh Circuit case, *Arlen*. See Opposition at 11, 20, and 22. The issue on appeal in *Arlen* was whether the government “could establish § 333(b)’s requirement of “intent to defraud or mislead” by showing that [Arlen] misled a government agency rather than the purchaser of the drugs. “ *U.S. v. Arlen*, 947 F.2d 139, 140-41 (5th Cir. 1991). In affirming the district court’s decision, the Seventh Circuit repeatedly reiterated that the government must demonstrate a specific intent to defraud or mislead an identifiable government agency:

We agree with the government that this result will not follow. While every conscious or willful violation of § 331 will carry a misdemeanor penalty, it will not always subject the violator to a felony sentence. To subject the defendant to a felony sentence requires the government to establish not only that the violation was willful but that it was ***committed with the specific intent to defraud or mislead an identifiable government agency.***

Arlen, 947 F.2d at 143.

“We therefore join our sister circuits’ interpretation of § 333(b) and hold that the government’s evidence is sufficient to make out a violation of this section where it shows that the defendant

intentionally violated § 331 *with the specific intent to defraud or mislead an identifiable government agency.*"

Arlen, at 143.

Arlen also recognized the importance of the plain text of the Section 331 provisions and followed the reasoning in *Bradshaw* that the plain text contemplates the FDA as the most likely government victim:

Several of the twenty acts § 331 proscribes concern only the government. *See* 21 U.S.C. § 331(e) (failure to permit FDA access to records and failure to make reports to the FDA); § 331(f) (refusal to permit FDA inspection); § 331(p) (failure to register with the FDA). As the *Bradshaw* court noted, "[a]fter reading these sections with § 333, it is clear that the FDA is the entity most likely to be defrauded under these provisions." *Bradshaw*, 840 F.2d at 874. Arlen's interpretation of § 333(b), that the government cannot be a defrauded or misled victim, would lead to the conclusion that there could never be a felonious violation of §§ 331(e), (f), or (p). Such a result would be contrary to the plain inclusive language of § 333(b), which contemplates both misdemeanor and felony violations for all § 331 offenses.

Arlen, at 142; *see* Defendants' Motion to Dismiss at 6-7 (discussing 331 provisions).

Thus, the Seventh Circuit decision in *Arlen* was focused almost entirely on determining whether the FDA was a proper object of the defraud and mislead provisions of Section 333(a)(2).

The Government, however, plucks the following citation from *Arlen*, which is dicta, to advance its limitless application of Section 333(a)(2):

The prosecution must prove beyond a reasonable doubt that a defendant intended to defraud or mislead someone, but the indictment need not specify the intended victim; the focus is on defendant's intent, not the victim's

identity. See *United States v. Hatch*, 926 F.2d 387 (5th Cir.), cert. denied, ___ U.S. ___, 111 S.Ct. 2239, 114 L.Ed.2d 481 (1991) (indictment for mail fraud, which requires proof of "any scheme or artifice to defraud," is sufficient even if it fails to define the victim); *United States v. Mizyed*, 927 F.2d 979 (7th Cir.), cert. denied, ___ U.S. ___, 111 S.Ct. 2065, 114 L.Ed.2d 470 (1991) (same)

Arlen, at 145.

Despite this, there are numerous problems with the Government's heavy reliance on this quotation from *Arlen*.

First, the court in *Arlen* was citing dicta from another Fifth Circuit decision in *U.S. v. Hatch*, 926 F.2d 387, 392 (5th Cir. 1991) when it stated that "the indictment need not specify the intended victim; the focus is on defendant's intent, not the victim's identity". *Arlen*, at 145. In *Hatch*, the defendant appealed his conviction for mail fraud based on a scheme to defraud aimed at the Union Parish Sheriff's Office which, through its sheriff's, controls a general fund. Hatch argued that the indictment was defective because under Louisiana law the USPO under Louisiana law has no legal status and therefore it was impossible to defraud the USPO. The court rejected this argument finding that the indictment stated the elements of the offense and "[n]aming the UPSO as the party defrauded did not prevent Hatch from ascertaining the charges against him." *Hatch*, at 392. Hatch further contended that the indictment failed to state a legally cognizable victim under federal law when it named the USPO as a victim. Again, the court rejected this argument reasoning that "[t]here is no

escape by Hatch from his conviction under the mail fraud statute as a result of the government's identifying the USPO as the party defrauded. Hatch's arguments must fail because federal law, not Louisiana law, controls application of the mail fraud statute. *Id.* at 392. Accordingly, *Arlen*'s reliance on *Hatch* is, at best, flawed since, in *Hatch*, the court's holding was based on an analysis of Hatch's challenges to an indictment in which the Government had *specifically identified the victim of the fraud* as the USPO.

Second, here, unlike *Arlen*, but similar to *Hatch*, the Government has elected to identify the supposed victims and, at a minimum, must therefore state an offense that is within the applicable statute, the FDCA. *United States v. Aleynikov*, 676 F.3d 71, 75-76 (2d. Cir. 2012) (citations omitted) ("Since federal crimes are 'solely creatures of statute,' "a federal indictment can be challenged on the ground that it fails to allege a crime within the terms of the applicable statute.").

As such, this Court should attribute no weight to the dicta from *Arlen* which was based on dicta from *Hatch* in deciding the Motion.

4. The Government Incorrectly Characterizes State Horse Racing Commissions as Quasi-Drug Regulators Akin to the FDA to salvage its Defective theory that Horse Racing Commissions are Consumer Protection Agencies Akin to the FDA

As tax collectors and regulators of gambling and lotteries, state racing commissions perform core functions that are separate and distinct from the functions performed by the FDA. It is also indisputable that, as commissions, state racing commissions are not “consumers” in the drug supply chain.

Furthermore, the commissions, as stewards of fair competition in horse racing tasked with the regulation and administration of permitted medications, are not responsible for setting drug standards, inspecting drugs, regulating the use of prescription drugs, or issuing permits to drug wholesalers.³ Opposition at 40. Race commissions do not approve drugs for consumption through a process which is anything like what the FDA does with new drug and investigational new drug applications which are subject to intense scrutiny and undergo a rigorous review process. For example, the race commissions do not have clinical trials to assess the efficacy of a drug or its safety. Nor do they *inspect* drugs the way that a wholesaler, consignee, purchaser, or government agency (*e.g.* the meat inspector in *Cattle Packing* or the Florida FDA in *Bradshaw*) involved in monitoring drugs does. The

³ The passage in *U.S. v. Mitcheltree*, 940 F.2d 1329, 1347 (10th Cir. 1991) cited to *Industrial Laboratories*, 456 F.2d at 909, *Cattle King Packing*, 793 F.2d at 937, and *Bradshaw*, 840 F.2d at 872. As reinforced in the Motion at 28, the state race commissions do not perform any of these functions. *Cattle King Packing* also did not involve drugs. It involved the inspection of meat. *Industrial Labs* involved a defendant chemist working at a company responsible for performing drug tests and analyses. It failed to perform drug standards set by a foreign country and lied to the government about performance of those tests on certain veterinary products.

commissions do not set drug standards. And they do not regulate prescription drugs by issuing permits, issuing licenses to sell or distribute drugs to wholesalers, or establishing off-label or extra-label uses of approved drugs.

To rebut this point, the Government highlights a patchwork of administrative provisions from 5 states (N.Y., N.J. Florida, PA, and DE) which reiterate several uncontroversial premises: the commissions establish schedules for drugs, test for the presence of illegal drugs, prohibit the possession of certain drugs by certain people on their grounds in connection with an athletic competition,⁴ and are concerned with protecting the health of the horse. Opposition at 33-40. The Government's emphasis on these provisions is instructive for several reasons.

First, the alleged *defrauding or misleading* in Counts 1-2 does not relate to protecting the health of the horse or concealing the health of the horse. In fact, each

⁴ The Government cites to 9 NYCRR §4012 and DE Admin Code §1001.15.12.2 for the premise that possession of non-FDA approved drugs is prohibited. Those provisions are also not incorporated into the permitted medication schedules in those states and, as discussed in the Motion at 39, n.34, the commissions specifically allow certain drugs which are not approved for use in animals and they disallow administration of FDA approved drugs in competitions if administered within periods prior to a race. Furthermore, the provision preceding the provision cited by the Government in DE also states that the use or possession of erythropoietin, darbepoietin, and perfluorcarbon emulsions is prohibited. Yet, darboetin is an FDA approved drug. See Del. Admin. Code § 1001-15.12.1; see also https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103951Orig1s5173_103951Orig1s5258lbl.pdf (FDA has *approved* Aranesp for use in the United States which contains darbepoietin alfa.).

of the allegations relate entirely to beating drug tests by “masking the presence of drugs,” evading drug tests, or making supposedly “undetectable” or “untestable” drugs. *See* Superseding Indictment, at ¶¶ 2, 3, 4, 5, 8, 15, 16, 18, 19 and 32.

Second, the “consumers” of the drugs in an athletic competition involving racehorses are the trainers and the administering veterinarians tasked with sourcing, purchasing, and administering drugs or medications to the racehorses. The numerous state laws which place the trainer in the role of the absolute insurer of the health of the competing horse plainly illustrate this point.⁵

⁵ See 9 NYCRR Section 4043.4; N.J.A.C. Section 13:71-23.6; Fla. Admin. Code 61D-6.008(3)(a)4 (defining those absolute responsibilities); *see also Dutrow vs. New York State Racing and Wagering Bd.* 949 N.Y.S.2d 241, 244, 97 A.D. 3d 1034, 1036-37 (App. Div. 3d Dep’t 2012) (finding that in light of the rebuttable presumption of trainer responsibility that arises under the rule, the tribunal below properly rejected the speculative “contamination” argument, instead relying upon positive test results, veterinary records, and the testimony of a veterinarian-pharmacologist to support the accusation.); *Hennessey vs. Department of Business and Professional Regulation, Division of Pari-Mutuel Wagering*, 818, So.2d 697, 699-700 (Fla. 1st DCA 2002) (“The trainer is singularly the best individual to hold accountable for the condition of a horse. The trainer is either going to be with the horse at all time or one of his or her employees or contractors is going to be with the horse at all times, whether the horse is racing on an individual day or is merely stabled at the track.”); *Division of Pari-Mutuel Wagering, Dept. Of Business Regulation v. Caple*, 362 So.2d 1350, 1354-56 (Fla. 1978); *Stokes vs. California Horse Racing Bd.*, 119 Cal. Rptr. 2d 792, 98 Cal. App. 4th 477 (“A trainer cannot disclaim responsibility for the performance of his duties merely because he assigns a task to another – whether a brother, an employee, or anyone else – who fails to properly perform the task. An innocent principal or employer is liable for the torts committed by an agent or employee while acting within the scope of the agency or employment, even if the agent or employee acts in excess of the authority or contrary to instructions.”); *Allen vs. Kentucky Horse Racing Authority*, 136 S.W.3d 54 (KY Ct.App. 2004) (same).

Nonetheless, even if the horse were viewed as the consumer of the drug in the interstate drug supply chain, the government still fails to state an offense. The FDA -- ***not*** the state race commissions or racetracks -- is the national government agency with the exclusive authority to approve new animal drugs *and* to protect consumers and the integrity of the drug supply chain. Indeed, but for the existence of the FDA, no approved animal drugs (OTC, prescription or otherwise) would enter that drug supply chain. Here, however, the supposed defrauding or misleading, as alleged, was directed at state race commissions to evade *drug testing in connection with an athletic contest* and was not directed at the FDA's approval process, its registration process, or any other lawful FDA function directly connected to its national regulation of the interstate distribution of drugs and the drug supply chain. This is yet another fatal blow to the government because such a theory falls far outside the ambit of the felony provisions of the FDCA.

Third, what the Government's selective citations to these provisions starkly reveals is that the commissions, as administrators of medication rules and testing protocols,⁶ are virtually indistinguishable from professional and collegiate associations regulating athletic competition, *e.g.*, Major League Baseball, the NFL,

⁶ Notably, many of these commissions also have delegated the authority to establish permitted medications to a private association, Association of Racing Commissioners International (ARCI) and have adopted their Controlled Therapeutic Medical Schedule.

the NHL,⁷ the U.S. Tennis Association, and PGA tour. The race commissions establish a permitted medication schedule, and they *test* for the presence of drugs and/or foreign substances and, much like Major League Baseball, the NFL, the NHL,⁸ the U.S. Tennis Association, and the PGA, such schedules and tests were designed to protect the health of the participants and the integrity of sport as described below:

- **NFL:** “First, these substances threaten the fairness and integrity of the athletic competition on the playing field. Second, the Parties are concerned with the adverse health effects of using Prohibited Substances.”⁹
- **MLB:** Major League Baseball’s Joint Drug Prevention and Treatment Program (“Program”) was established by agreement of the Office of the Commissioner of Baseball and the Major League Baseball Players Association (the “Commissioner’s Office,” the “Players Association” and, jointly, the “Parties”) to: (i) educate Players on the risks associated with the use of Prohibited Substances (defined in Section 2 below); (ii) deter and end the use of Prohibited Substances by Players; and (iii) provide for, in keeping with the overall purposes of the Program, an

⁷ The NHL follows the World Anti-Doping Association (WADA) *available at* https://www.usada.org/wp-content/uploads/wada_2021_english_summary_of_modifications_.pdf;

⁸ The NHL follows the World Anti-Doping Association (WADA) *available at* https://www.usada.org/wp-content/uploads/wada_2021_english_summary_of_modifications_.pdf;

⁹ The NFL Policy on Performance Enhancing Substances (2020), at 3 *available at* <https://nflpaweb.blob.core.windows.net/website/Departments/Salary-Cap-Agent-Admin/2020-Policy-on-Performance-Enhancing-Substances.pdf>.

orderly, systematic, and cooperative resolution of any disputes that may arise.”¹⁰

- **GOLF:** “The PGA TOUR has developed this Anti-Doping Program (the “Program”) to protect the integrity that is inherent in the sport of golf, and to ensure the health and safety of all players.”¹¹
- **TENNIS:** “The purpose of this 2021 Tennis Anti-Doping Programme (Programme) is to maintain the integrity of tennis and to protect the health and rights of Players.”¹²
- **NCAA:** “To further the protection of competing student-athletes — specifically, so that no one participant might have an artificially induced advantage or feel pressured to use substances or methods to gain an unfair competitive advantage, the NCAA drug-testing program was created. This program provides for year-round, championships and post-season bowl games drug testing..... This list consists of substances generally purported to be performance enhancing and/or potentially harmful to the health and safety of the student- athlete.”¹³

¹⁰ Major League Baseball Joint Drug Prevention and Treatment Program, at 5, *available at* <http://www.mlb.com/pa/pdf/jda.pdf>.

¹¹ PGA Tour Anti-Doping Manual at 12, *available at* https://www.usga.org/content/dam/usga/pdf/2018/2017-2018_Anti_Doping_Manual.PDF. The Manual contains comprehensive drug-testing policies.

¹² 2021 Tennis Anti-Doping Programme, at 1 (2021), *available at* <https://antidoping.itftennis.com/media/317953/317953.pdf>

¹³ NCAA Drug Testing Program (2020-2021), at 6, *available at* https://ncaaorg.s3.amazonaws.com/ssi/substance/2020-21SSI_DrugTestingProgramBooklet.pdf

Therefore, the mere existence of this drug testing framework does not convert the state racing commissions into a drug regulator akin to the FDA any more than the existence of robust PED drug testing protocols might convert MLB, NCAA, the PGA, etc. into quasi-drug regulators akin to the FDA. Similarly, the performance of any of these functions does not substantially (and artificially) broaden the core functions of the commissions and therefore elevate the commission to the position of a quasi-drug regulator with any of the attributes of the FDA or its state counterparts concerned with consumer protection and the integrity of the drug supply chain.

Applying this flawed reasoning would lead to an absurd result which Congress could not have intended in passing the FDCA and implementing the felony provisions found at Section 333(a)(2). In fact, under this theory, the MLB, NFL, the USTA, the PGA, or the NCAA are drug regulators comparable to the FDA.

5. Despite the Government's Assertions, the Superseding Indictment is Defective because it Never Alleges that the FDA is an Object of the Defrauding or Misleading in Counts 1-2 or in the Introduction (pages 1-10 of the Superseding Indictment).

The Government asserts that “[a]s noted above, *the Indictment does allege that the FDA is among the agencies misled and defrauded through the defendants' misbranding offenses.*” Opposition at 30. (emphasis ours). This is flatly contradicted by the Superseding Indictment itself. There is not a single sentence in

the introductory portions of the Superseding Indictment or in Counts 1-2 that states that the “FDA,” as opposed to some nebulous “federal regulator” or “agency” was defrauded or mislead by any defendant at any time by any means. See Superseding Indictment, at ¶2,3,4, 8, and 15.

- ¶2: “By evading PED prohibitions and deceiving ***regulators and horse racing authorities***, among others”
- ¶3: “the scheme participants routinely defrauded and misled ***government agencies, including federal and state drug regulators,¹⁴ U.S. Customs and Border Protection, various state horse racing regulators, certain horse owners, and the betting public***.”
- ¶5: “Navarro and his co-conspirators concealed the purchase and administration of adulterated and misbranded PEDs from ***federal and state government agencies, racing officials, the betting public and others***. Navarro executed this scheme by using PEDs designed to evade drug tests, physically concealing containers of PEDs and drug paraphernalia from ***state regulators and race officials***, administering and directing others to covertly administer PEDs and shipping certain products designed to mask the presence of PEDs through a straw purchaser.”
- ¶8: Fishman and his co-conspirators further concealed the true nature and purpose of those adulterated and misbranded PEDs in order to defraud and mislead, among others, ***federal and state government agencies and regulators***.”

¹⁴ It is entirely unclear who a “federal drug regulator” might be. The Drug Enforcement Agency (DEA), the FDA, the Department of Health and Human Services (HHS), the Center of Medicare and Medicaid-Services (CMS) which regulates drugs under Part D and contracts with specific organizations to manage Part D compliance, the Center for Disease Control and Prevention (CDC), among others, could all potentially constitute “federal drug regulators.”

- ¶15: “In many cases the PEDs were designed to be untestable on drug tests, in order to defraud or mislead **federal and state regulators, racing official, and the betting public**. In many cases, the customized PEDs contained false and misleading labeling containing, for example, the terms “for research purposes only” or “homeopathic” in order to defraud and mislead **federal and state regulators** into believing the products were not intended for the purpose of doping racehorses.”¹⁵

The absence of any reference to the FDA in connection with any of the allegations of defrauding or misleading compels the conclusion that the grand jurors were not instructed that the FDA was the object of the alleged conspiracies in Counts 1-2. *Stirone v. United States*, 361 U.S. 212, 215-16 (1960) (“Ever since *Ex parte Bain*, 121 U.S. 1. was decided in 1887 it has been the rule that after an indictment has been returned its charges may not be broadened through amendment except by the grand jury itself.”).¹⁶

¹⁵ These ambiguities regarding the supposed victims are further evidenced in the Government’s shifting positions: Compare ECF-283 at 11 at ¶ 16, and 22 at ¶ 32 (listing state regulators and race officials as the objects of the defrauding or misleading) with 26:9-12 (Transcript of 11.17.20 Status Conference) (emphasis ours) (“With respect to misbranding, **the racetracks, racing commissions, owners, competitors** are all among people for whom -- or who are in the minds of the defendants charged with misleading and participating.”) and with Opposition at 4-5 (claiming that the Superseding Indictment by incorporating its introductory language -- which comprises more than 10 pages -- incorporates those factual allegations therein which discuss *amorphous unidentifiable federal and state regulators*, the betting public, certain horse owners, race officials, state race regulators, the U.S. Customs and Border Protection as potential victims of the defrauding and/or misleading offense under the FDCA).

¹⁶ See *United States v. Twersky*, No. S2 92 Cr. 1082 (SWK), (S.D.N.Y. June 29, 1994) (citation omitted) (“As a legal advisor to the grand jury, the prosecutor must give the grand jury sufficient information concerning the relevant law ‘to enable it intelligently to decide whether a crime has been committed.’”). Moreover, courts regularly dismiss indictments based on erroneous instructions to the grand jury about the charged offense. See, e.g., *United States v. Bowling*, 108 F. Supp. 3d 343, 352-53 (E.D.N.C. 2015) (dismissing multiple counts because of “the government’s erroneous legal instruction to the grand jury”); *United States v. Stevens*, 771 F. Supp. 2d 556, 567-68 (D. Md. 2011) (dismissing indictment where the prosecutor gave erroneous advice

For this reason, Counts 1-2 must be dismissed.

6. The Government Citations to U.S. Customs Cases Fails to Support its Limitless Application of the FDCA Theory

In its Opposition, the Government attempts to strengthen the premise that the FDCA is so broad and all-encompassing that it reaches state race commissions and racetracks by referencing court decisions involving U.S. Customs. In so doing, the Government miscites at least two of those cases.

First, in *United States v. Vinod Patwardhan*, 2018-cr-172 (E.D. Cal. March 4, 2019) (Second Superseding Indictment at ECF 79), the Government charged the defendant with a violation of the specific offense prong *and the “defraud” prong* of Section 371. **Exhibit A.** In Count 1 of the Superseding Indictment, the government also alleged 4 separate underlying violations (including smuggling in violation of 18 U.S.C. Section 545). **Ex. A.** at 6. In Count 1, the specific offense prong – which is at issue here – never referenced a specific victim (government agency or otherwise) that was mislead or defrauded. *Id.* at 6. Nonetheless, the government alleged that the defendant had intentionally conspired to “defraud the United States of an concerning its governmental functions and rights namely to interfere with or obstruct the lawful

to the grand jury); *United States v. Cerullo*, No. 05-cr-1190 (S.D. Cal. Aug. 28, 2007) (dismissing indictment where the prosecutor’s failure to accurately and fairly explain an important legal issue “misled the grand jury” and “prejudiced the Defendant”); *United States v. Breslin*, 916 F. Supp.438 (E.D. Pa. 1996) (dismissing the indictment on several grounds, but labeling “most disturbing” the prosecutor’s erroneous legal instructions to the grand jury).

functions of the FDA, HHS, and DHS by deceit, craft, trickery, and dishonest means. *Id.* In other words, the assertion in the Opposition, at 13, “that customs may be the object of deceit” in a 371-conspiracy alleging a violation of Section 333(a)(2) is not supported by the charging documents in *Patwardhan* or by the Ninth Circuit’s decision. In fact, that decision does not even contain the words “customs,” “border protection,” or “DHS.” The decision’s discussion of sufficiency of the evidence at trial to sustain his *substantive misbranding convictions* was instead premised entirely on the following:

Patwardhan told his staff not to give patients foreign medicine for at-home use after a patient's mother expressed concern about one label, which was written in Hindi. Patwardhan never informed his patients that the drugs administered to them during in-office treatments were not FDA-approved. To the contrary, the IV bags used to administer the foreign medicine contained only the names of the FDA-approved counterparts. Additionally, there was evidence that Patwardhan's staff hid foreign medicine during an audit, and used the codes corresponding to the FDA-approved drugs, not the foreign medicines that had actually been used, when billing Medicare for reimbursement.

U.S. v. Patwardhan, 422 F. App'x 614, 616-17 (9th Cir. 2011).

The Government makes the same error in its citation to *United States v. Vitek Supply Corp.*, 144 F.3d 476, 480 (7th Cir. 1998). Opposition at 13. It states that “affirming conviction of defendant who engaged in a conspiracy to distribute adulterated or misbranded animal drugs with the intent to defraud “Customs and the FDA.” See Opposition at 13. This is incorrect. Unlike *Patwardhan*, the defendants in *Vitek Supply Corp.* were not even charged with a 371 conspiracy to specifically

violate Section 333(a)(2) or any other misbranding provision of the FDCA. According to the docket sheet attached as **Exhibit B**, the defendants were charged under the “defraud prong” of Section 371 with conspiracy to defeat the lawful functions of the FDA and U.S. Customs. **Ex. B.** The defendants were also charged with substantive misbranding counts and sentenced to 4 years of probation. **Exhibit B.**

Third, in *U.S. v. Orrego-Martinez*, 575 F.3d 1, 5 (1st Cir. 2009), the Indictment itself never referenced U.S. Customs and instead alleged:

That the object of the unlawful conspiracy was to unlawfully introduce into interstate commerce and import into the U.S. adulterated devices, *Silicex*, a liquid injectable silicone and *Kathy Swed*, and non-approved drugs, *Lignocaine Injection BP 2%* and *Kenacort* for the purposes of injecting said devices and drugs into human beings for pay and profit.

See U.S. v. Carlos Orrego Martinez, 02-cr-465-DRD (D. P.R. Dec. 5, 2002) (Indictment, ECF-4). (

The *Orrego-Martinez* case has a peculiar procedural history which began with a first trial resulting in a hung jury/mistrial and a judgment of acquittal. Defendant was indicted on new charges three months later and convicted. One of the main arguments raised on appeal by the defendant was “issue preclusion” contending that the government had based its theory on defrauding customers which the first jury had rejected, and then, in the second trial, switched its theory of the fraud mid-trial

from a theory of deceiving patients about the nature of the drugs they were receiving (end-users) to a theory that focused on deceiving U.S. Customs and regarding the importation of the unapproved drugs into the U.S. The First Circuit reasoned that this was an overstatement given that “Customs” was a “passing reference”:

During the 12-day trial, the government offered a smattering of evidence concerning the efforts to mislead U.S. Customs, but it focused overwhelmingly on the false statements made to the clients (other than the five clients listed in the wire-fraud indictment) — *e.g.*, the same type of misrepresentations concerning the identity and safety of the implants and defendant's status as a physician that were presented at the first trial. The government did the same during closing argument, ***making only a passing reference to the U.S. Customs matter.***

Orrego-Martinez, 575 F.3d at 5. (emphasis ours).

The First Circuit continued:

It is true, as the government points out, that the evidence of defendant's intent to deceive U.S. Customs provides an adequate foundation for invoking § 333(a)(2)'s felony provision. Various courts have held, and defendant does not dispute, that the government can satisfy § 333(a)(2) by establishing an intent to defraud or mislead a government enforcement agency. *See, e.g., United States v. Arlen*, 947 F.2d 139, 141-45 (5th Cir. 1991); *United States v. Bradshaw*, 840 F.2d 871, 873-75 (11th Cir. 1988).

Id. at 6.

In this last quotation from *Orrego-Martinez*, there is no discussion or analysis of Section 333(a)(2) and neither of the cases cited by *Orrego Martinez* – not *Arlen* or *Bradshaw* – support the premise that U.S. Customs is a proper object of the defraud/mislead clause of Section 333(a)(2). *Arlen* involved the FDA and *Bradshaw*

involved the Florida FDA. *Bradshaw*'s holding that the state-counterpart to the FDA was a proper object of that clause was also based entirely on an exacting analysis of the history and purpose behind the FDCA and its plain language. *Bradshaw*, 840 F.2d at 873-74. The same level of analysis (or any analysis at all) is entirely missing in the First Circuit decision in *Orrego-Martinez*. As such, this court should attribute no weight to *Orrego-Martinez*' passing reference to Customs in rendering a decision on Defendants' Motion to Dismiss.¹⁷

7. *Milstein* is Inapposite and is not Persuasive Authority.

The Government urges this Court to find that *U.S. v. Milstein*, 401 F.3d 53, 69 (2d Cir. 2005) – which involved a technical violation of the Prescription Drug Marketing Act (PDMA) which is part of Section 331 – supports their limitless application of the FDCA. The PDMA obligates a distributor to provide both wholesalers and the consumers or purchasers of drugs with pedigree paperwork

¹⁷ Even if *Orrego-Martinez*' two sentences about U.S. Customs were correct as a matter of law – which we argue they are not – at least there is some textual and historical support for potentially including U.S. Customs as a proper object of Section 333(a)(2). For example, Section 331(d) and Section 331(t) which are the predicate violations which must be violated with the “intent to defraud or mislead” under Section 333(a)(2) specifically reference the “*introduction of*” and/or the “*importation of*” drugs into the U.S. See 21 U.S.C. Sections 331(d) and (t). In other words, if you introduce drugs into the U.S. or import them into the U.S., Customs not the FDA is primarily responsible for enforcing the Customs laws which govern such importations. The FDCA and its predecessor statute in 1906 also carved out an exemption for *exports* of drugs under 21 U.S.C. Section 381(e) and was therefore concerned with protecting U.S. consumers from foreign adulterated or misbranded drugs or food and at the same time preoccupied with encouraging free trade and incentivizing the exportation of food and drugs to foreign countries. 18 U.S.C. Section 381.

which accurately lists the history of transactions from the original manufacturer. *See* 21 U.S.C. Section 331(t) (making it a misdemeanor to distribute prescription drugs without providing a history of transactions from the original manufacturer). Milstein provided phony pedigree docs and was therefore prosecuted. In upholding his conviction, this Circuit stated:

Count Five charged Milstein with failing to provide his customers with the required pedigree information "with the intent to defraud and mislead." The "intent to defraud" element converts conduct that would otherwise be a misdemeanor into a felony. *See* 21 U.S.C. § 333(a)(1), (2). The District Court charged the jury that "intent to defraud" includes intent to defraud not only the wholesale distributors who made direct purchases from Milstein but also retail consumers and government agencies.

U.S. v. Milstein, 401 F.3d 53, 69 (2d Cir. 2005)

This Circuit also noted that, "[b]y misleading governmental agencies, and "thereby frustrating their efforts to protect the public," Milstein "indirectly misled and defrauded the public," thus contravening the "overriding congressional purpose [of] consumer protection" embodied in these provisions." *Milstein*, 401 F.3d at 69. (emphasis ours).

Accordingly, *Milstein's* holding is limited to recognizing that both the FDA and consumers in the drug supply chain are proper objects of Section 333(a)(2) of the FDCA.

CONCLUSION

The Court should dismiss Counts 1-2 of the Superseding Indictment with prejudice. Both the plain text, legislative history, and purposes underlying the FDCA compel dismissal of those Counts as does the application of the Rule of Lenity.